

Employee Benefits & Executive Compensation ADVISORY

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Health Care Reform Guidance Update: New Prescription Requirement for OTC Medicines and Drugs Will Impact Administration of FSAs, HRAs and HSAs; and Guidance on Waiver Process for “Mini-Med” Plans

On Friday, September 3, two new pieces of guidance were issued relating to requirements under the Patient Protection and Affordable Care Act (PPACA):

- The IRS issued Notice 2010-59 (the “OTC Notice”), which clarifies the limitation imposed by the PPACA on the eligibility of over-the-counter (OTC) drugs and medicines for tax-free reimbursement under an employer-sponsored health plan.
- The Department of Health and Human Services (HHS) issued guidance for employers regarding how to obtain a waiver from the restricted annual limits imposed under PPACA. The guidance is issued in the form of a memorandum posted on the HHS website at http://www.hhs.gov/ociio/regulations/patient/ociio_2010-1_20100903_508.pdf.

This advisory addresses the impact that this guidance will have on group health plans and what actions need to be taken now in response to the guidance.

New Prescription Requirement for OTC Medicines and Drugs

Section 9003 of PPACA requires that, beginning January 1, 2011, OTC medicines and drugs (other than insulin) must be “prescribed” in order to qualify as “medical care” for purposes of employer-sponsored health plans (including Health FSAs and HRAs) and Health Savings Accounts (the “OTC Rule”).

This change will have a dramatic impact on the way that OTCs are purchased and used by individual consumers. Some are predicting that health care costs will increase as individuals schedule physician office visits to get “OTC prescriptions,” or alternatively, opt for more expensive “prescription-only” medications to ensure coverage under their plans. At a minimum, the OTC Notice has the potential to cause confusion for consumers as they seek to understand the new prescription requirement for OTCs under their health plans. Likewise, third party administrators (TPAs) must employ new procedures to ensure that the OTC prescription requirement is satisfied.

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The OTC Notice answers a number of questions arising under the new OTC prescription requirement, including the following:

- When is a medicine or drug considered “prescribed”? In other words, is a physician’s recommendation enough, or must all of the requirements applicable under state law for a valid prescription be satisfied?
- What type of substantiation is required to ensure that a medicine or drug available OTC has actually been “prescribed”?
- How does the new OTC Rule’s effective date affect plans and employee FSA elections that are already in place (e.g., plans that have fiscal plan years or calendar year plans with grace periods)?
- How does the OTC Rule impact the use of health debit cards to purchase OTC medicines and drugs?

This alert provides an overview of the guidance included in the OTC Notice, and concludes with a synopsis of the impact on plan sponsors and TPAs.

Understanding the New OTC Rule and the OTC Notice

The basic rule

Section 9003 of PPACA provides that expenses for OTC drugs or medicines (other than insulin) incurred on or after January 1, 2011, will only be considered “medical care” for purposes of Code Sections 105 and 106 (health plans, including Health FSAs and HRAs), 220 (Medical Savings Accounts) and 223 (Health Savings Accounts) if they are “prescribed.”

What is a medicine or drug?

The determination as to whether a particular OTC item is a medicine or drug is important because the new rules do not apply to OTC medical supplies and equipment, such as contact lens solutions, bandages, crutches or durable medical equipment or diagnostic devices such as blood sugar test kits. Such OTC items may continue to be purchased without a prescription, and once such items are identified, currently compliant health debit card systems can continue to operate as they do today with respect to such items.

Unfortunately, the OTC Notice does not provide further guidance as to what is a “medicine or drug.” Existing guidance under IRS regulation 1.213-1(e)(2) is circular, providing that “medicine or drug” includes any items that are “generally accepted as falling within the category of medicine and drugs.” However, insulin is not a medicine or drug for purposes of this rule.

When is a medicine or drug (other than insulin) considered “prescribed” for purposes of the OTC Rules?

The OTC Notice clarifies that an OTC drug is considered prescribed for purposes of the new rule if the individual obtains a “prescription” for such medicine or drug (even though a prescription is not legally required to obtain the medicine or drug). A prescription is defined as an electronic or written order for a medicine or drug that meets the legal requirements of a prescription in the state in which the medical expense is incurred, and that is issued by an individual authorized to issue a prescription in that state.

Example #1: Bob lives in California. On January 2, 2011, Bob has a headache. He goes to his physician, who recommends that Bob take two aspirin and call him in the morning. Bob purchases a bottle of aspirin for \$5.76. On January 3, 2011, he submits the receipt for aspirin to his FSA administrator. The FSA administrator must deny the claim because Bob did not obtain a prescription for the aspirin. A general physician recommendation (oral or otherwise) that does not satisfy state law will not qualify as a prescription.

Example #2: Same facts, except that Bob's physician actually writes Bob a "prescription" for aspirin. Since the expense was incurred in California, the prescription must satisfy California's requirements for prescriptions in order for the aspirin to be reimbursable. California requires, among other things, that the prescription identify the name and quantity of the drug, and that it be signed (if in writing) and issued by certain medical practitioners (e.g., a physician, physician assistant or nurse midwife). If all of the applicable state law requirements are satisfied, Bob can be reimbursed for the aspirin under his FSA plan.

Practice Pointer: The OTC Notice prerequisite that state law requirements for a prescription be satisfied is somewhat awkward in that it requires application of state rules for tax purposes that are NOT required to be satisfied for an individual to purchase a medication—since the medicine is available OTC, after all. Most TPAs are not accustomed to monitoring, and ensuring compliance with, the prescription rules applicable under each state's laws. Nevertheless, the OTC Notice provides a substantiation solution that will ease administration of this otherwise burdensome compliance requirement. See "What substantiation is required for OTC drugs or medicines" below for more details.

What substantiation is required for OTC drugs or medicines (other than insulin)?

The OTC Notice indicates that proper substantiation is provided if the participant provides either of the following:

- a receipt from the pharmacy that identifies the purchaser (or the individual to whom the prescription was issued), the date, the amount and the Rx number; or
- any other "traditional" manual substantiating documentation without an Rx number (e.g., a sales receipt that identifies the medicine or drug, amount and date purchased), provided the prescription from an authorized issuer is provided.

The first method of substantiation, consistent with prior informal IRS advice, allows the TPA to use the Rx number as a proxy for eligibility under Section 213. Under the latter method, the participant can apparently pick up the OTC and pay for it at the front of the store with no pharmacist interaction, but then the burden falls on the TPA to ensure that that the prescription satisfies the applicable requirements for a prescription in the state in which the expense was incurred. In either case, the physician must actually prescribe the drug, but in the latter case the prescription apparently need not be "filled" by a pharmacist.

Practice Pointer: TPAs may find it difficult, if not impossible, to track "prescription" requirements in each state. Therefore, many TPAs may decide to limit approved substantiation to a receipt from the pharmacy with the Rx number unless other ways to ensure that the prescription meets applicable state requirements can be found.

What is the impact of the OTC Notice on use of debit cards to purchase OTC drugs or medicines?

Currently, health debit card systems allow for the purchase of eligible medical expenses (including OTC medicines and drugs) under two alternate adjudication systems. First, arrangements that satisfy IRS requirements for point-of-sale adjudication (so-called "IIAS," or Inventory Information Adjudication Systems) can be employed by any merchant, regardless of whether it is a health care merchant.¹ Alternatively, certain merchants that qualify as "90% Merchants" can allow for health debit card use without an IIAS system. A 90% Merchant would include any drug store or pharmacy whose gross receipts for medical care (including eligible OTC items) during the prior taxable year equals or exceeds 90% of the store's gross receipts (determined on a location-by-location basis).² As noted below, whether a merchant is a 90% Merchant or any other merchant that employs an IIAS compliant system makes a huge difference under the OTC Notice.

The OTC Notice states that current health debit card systems are "not capable of substantiating compliance with the [new OTC requirement]." As a result, the Notice concludes that health FSA and HRA debit cards may not be used to purchase OTC medicines or drugs on and after January 1, 2011 (subject to the January 15 transition period discussed below). These comments start with the premise that current IIAS arrangements are unable to determine whether a valid prescription was issued. However, the OTC Notice solicits comments "on new designs for debit card systems that could provide substantiation that an over-the-counter medicine or drug was prescribed." Thus, an electronic debit card point-of-sale system (IIAS or otherwise) that requires proof that a valid prescription has been issued prior to releasing funds should be acceptable to IRS. More guidance on this issue would be welcome.

In the interim, participants may continue to use health debit cards for eligible OTC medical items other than medicines or drugs under an IIAS system. In addition, compliant cards can continue to be used at drug stores and pharmacies that qualify as 90% Merchants, since such stores are not currently required to substantiate medical items at the point of sale or otherwise use an IIAS system. Moreover, in determining whether a store is a 90% Merchant, otherwise eligible OTC medicines and drugs continue to count as eligible medical expenses, regardless of whether a prescription has been issued.

Practice Pointer: The OTC Notice indicates that the IRS will not challenge the use of debit cards for OTC drugs and medicines through **January 15, 2011**, provided the other requirements set forth in the applicable debit card guidance (e.g., Notice 2006-69) are satisfied.

What is the effective date of the new OTC Rule?

The new rule applies for OTC medicines or drugs (other than insulin) incurred on or after January 1, 2011, without regard to the plan year of the plan. Thus, a plan with a fiscal plan year must begin complying with the rule mid-plan year.

Example: ABC sponsors a health FSA with an October 1 through September 30 plan year. Bob purchases Claritin on December 1, 2010, without a prescription. He submits his reimbursement request and is subsequently reimbursed. On January 2, 2011 (same plan year), Bob again purchases Claritin without a prescription. He submits his request for reimbursement, but this time, it is denied because he did not obtain a prescription.

¹ See IRS Notice 2006-69.

² See IRS Notice 2007-2 for more information on the 90% rule.

Practice Pointer: Can Bob change his health FSA election as a result of the new rule? Although the OTC Notice does not specifically address election changes, a literal interpretation of the existing change rules and recent, informal remarks from Treasury officials would suggest that Bob could *not* change his election solely as a result of the rule change.

Also, expenses for OTC drugs and medicines incurred during the two-and-a-half-month grace period following the end of a 2010 calendar plan year must be accompanied by a prescription.

Practice Pointer: OTC drugs purchased prior to January 1, 2011, may be reimbursed tax-free on or after that date. Thus, if an HSA participant purchases OTC drugs or medicines in 2010 without a prescription, but does not take an HSA distribution for such expenses until 2011, the distribution in 2011 is still tax-free (so long as the expenses were otherwise for medical care).

Do cafeteria plans and HRAs need to be amended?

The OTC Notice states that plans that previously covered OTC drugs or medicines must be amended to reflect the new OTC Rule. Fortunately, the OTC Notice allows plans to be retroactively amended effective January 1, 2011 (or January 15, 2011, with regard to debit card purchases), so long as the amendment is adopted no later than June 30, 2011.

What Steps Should Be Taken at This Time In Light of the New OTC Rule?

Even though the new OTC Rule is not effective until January 1, 2011, plan sponsors and administrators should take steps now to ensure a smooth transition. Steps to undertake include:

- communicating the new OTC Rule to participants prior to 2011 enrollment (and likely again in December) to ensure that participants take the new OTC Rule into consideration when making their new elections;
- checking with TPAs and health debit card processors to ensure that OTC medicines and drugs will not be reimbursed starting January 1, 2011 (January 16 for health debit card purchases eligible for the transition rule), unless the prescription requirement is satisfied;
- implementing new processes and procedures to ensure that every claim for an OTC medicine or drug has a valid Rx number or an accompanying prescription that satisfies all of the requirements of state law; and
- adopting plan amendments (prior to January 1, 2011, if possible) to implement the new OTC Rule.

Application Process for Waiver from Restricted Annual Limits

Section 2711(a)(2) of the Public Health Service Act (PHSA) as added by PPACA provides that for plan years beginning on or after September 23, 2010, and before January 1, 2014, group health plans may impose “restricted” annual limits on the dollar value of essential health benefits (as defined in section 1302(b) of PPACA) as determined by the Secretaries of HHS, Labor and Treasury (collectively, the “agencies”). For plan years beginning on or after January 1, 2014, no annual dollar limits on essential benefits may be imposed. These rules apply to grandfathered group health plans, as well as new group health plans.

“Restricted” Annual Benefits and Limited Benefit Plans

The maximum “restricted” annual dollar limit that may be imposed on essential benefits was set forth in interim final regulations (IFR) published by the agencies on June 28, 2010, as follows:

- For plan years beginning on or after September 23, 2010, but before September 23, 2011—\$750,000;
- For plan years beginning on or after September 23, 2011, but before September 23, 2012—\$1.25 million; and
- For plan years beginning on or after September 23, 2012, but before January 1, 2014—\$2 million.

These annual limitations are problematic for a class of health plans that provides limited coverage, typically referred to as “limited benefit” plans or, sometimes, “mini-med” plans. These plans are used by employers to provide some form of low-cost health insurance to certain employees, such as part-time employees and seasonal workers. For such employees, a “limited benefit” plan or “mini-med” plan may be the only affordable health coverage available to the employee. Applying the annual limits to such plans could mean that the coverage is no longer affordable, and could result in a loss of coverage. [Note: Mini-med plans should not be confused with limited hospital indemnity and specified disease coverages, which often are completely exempt from PPACA as excepted benefit coverage.]

In recognition of this issue, the IFR provided that these restricted annual limits may be waived by the Secretary of HHS if compliance with the IFR would result in a significant decrease in access to benefits or a significant increase in premiums. The preamble to the IFR further provided that guidance from HHS regarding the scope and process for applying for such a waiver would be issued in the near future. The memorandum issued by HHS on September 3, 2010 (the “HHS memorandum”), provides such guidance.

The HHS memorandum does not provide details about the standards that will be applied in determining whether waivers are granted; for example, the memorandum does not indicate what the HHS will consider to be a “significant” increase in premiums. The HHS memorandum does, however, set forth the timing for applications, the information that must be included and deadlines by which HHS will process the applications.

Waiver Process

What plans are eligible for the waiver?

Waivers are available only for plans that were in existence before September 23, 2010.

When does the waiver application have to be submitted?

For plan years beginning before November 2, 2010, the waiver application must be submitted at least 10 days in advance of the start of the year. Otherwise, the application must be submitted at least 30 days before the beginning of the plan year.

³ The regulatory agencies have not yet defined “essential health benefits.” In the absence of further guidance, the agencies have stated that for enforcement purposes, the agencies will take into account good faith efforts to comply with a reasonable interpretation of the statute.

⁴ The restrictions on annual dollar limits do not apply to grandfathered individual market policies.

When will HHS process the waiver application?

HHS will process complete requests generally within 30 days of receipt, but for plan years beginning before November 2, 2010, HHS will process the application no later than five days in advance of the year.

If granted, for how long will a waiver apply?

Waivers will be granted initially only for the first plan year beginning between September 23, 2010, and September 23, 2011. New waiver applications must be submitted for later years and HHS may change the approval process in the future.

What information must be included in the application?

The application must include the following information:

- the terms of the plan for which a waiver is sought;
- the number of individuals covered by the plan;
- the annual limit(s) and rates applicable to the plan;
- a brief description of why compliance with the IFR on annual limits would result in a significant decrease in access to benefits for those currently covered by the plan, or significant increase in premiums (or contributions in the event of a self-funded plan) paid by those covered by the plan, along with any supporting documentation; and
- an attestation, signed by the plan administrator or chief executive officer of the issuer of the coverage, certifying (1) that the plan was in force prior to September 23, 2010; and (2) that the application of restricted annual limits to the plan would result in a significant decrease in access to benefits for those currently covered by the plans, or a significant increase in premiums paid by those covered by the plan. The plan administrator or CEO should retain documents in support of the application for potential examination by HHS.

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